



# 6

Docket No. 12688120940

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**Certificate of Mailing/Transmission (37 C.F.R. § 1.8(a)):**

[X] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to the Assistant Commissioner for Patents, Washington D.C. 20231.

[ ] Pursuant to 37 C.F.R. § 1.6(d), I hereby certify that this paper and all enclosures are being sent via facsimile on the date indicated below to the attention of Examiner \_\_\_\_\_ at Facsimile No. \_\_\_\_\_ at \_\_\_\_\_ a.m./p.m.

Dated: August 7, 2001

Name of Person Certifying: Peggy Nichols  
Printed Name: Peggy Nichols**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Charles A. Nicolette	Assignee:	Genzyme Corp.
Filing Date:	March 19, 2001	Examiner:	Not Yet Assigned
Serial No.:	09/812,238	Group Art Unit:	1614
Title:	THERAPEUTIC ANTI-MELANOMA COMPOUNDS		

Assistant Commissioner for Patents  
Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

**I. Timing of the Information Disclosure Statement:**

This Information Disclosure Statement is filed:

- ☐ With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).
- ☐ Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.
- ☒ Before the mailing date of a first Office action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 50-1189 for any fees required pursuant to 37 C.F.R. §§ 1.17(p) or 1.17(i)(1).

This Information Disclosure Statement is filed:

- ☐ After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and the Commissioner is hereby authorized to charge Deposit Account No. [ ] for the fee (\$180) set forth in 37 C.F.R. § 1.17(p) and any additional required fees.

This Information Disclosure Statement is filed:

- ☐ After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

The undersigned certifies that:

- ☐ Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

## II. Copies of the Cited Items:

- ☒ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.
- ☐ Copies of only the following items listed on the attached Form PTO-1449 are enclosed: \_\_\_\_\_.
- ☐ Copies of those items which are marked with an asterisk (\*) in the attached Form PTO-1499 are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application No. \_\_\_\_\_, filed \_\_\_\_\_ and relied upon in this application for an earlier filing date under 35 U.S.C § 120. See 37 C.F.R. § 1.98(d).

- ☐ Copies of those items which are marked with an asterisk (\*\*) in the attached Form PTO-1499 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

**III. Concise Explanation of Relevance:**

- ☒ A concise explanation of relevance of the items listed on Form PTO-1449 is not given.
- ☐ A concise explanation of relevance of [some of] the items listed on Form PTO-1449 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references (copy attached).

**IV. Conclusion:**

Citation of the above documents shall not be construed as:

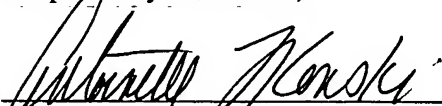
1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

The Commissioner is hereby authorized to charge Deposit Account No. 50-1189 Docket No.: 126881209400 for any additional fees required in connection with the filing of this Information Disclosure Statement.

DATE: August 7, 2001

Respectfully submitted,

By:   
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Form PTO-1449	Docket No. 126881209400	Appl. No. 09/812,238
INFORMATION DISCLOSURE STATEMENT	Applicant(s) Charles A. NICOLETTE	
(use several sheets if necessary)	Filing Date: March 19, 2001	Group Art Unit: 1614

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date (if appropriate)
	1.	07/28/87	4,683,195	Mullis et al.			
	2.	07/28/87	4,683,202	Mullis			
	3.	06/28/88	4,754,065	Levenson et al.			
	4.	01/24/89	4,800,159	Mullis et al.			
	5.	08/08/95	5,440,013	Kahn			
	6.	11/17/98	5,837,249	Heber-Katz et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Translation YES NO
	7.	08/01/96	WO 96/23060	The Government of the United States of America			

## OTHER DOCUMENTS

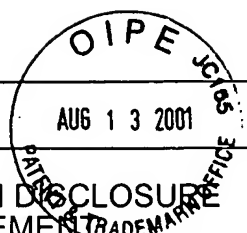
(including author, title, date, pertinent pages, etc.)

Examiner Initials	Ref. No.	Title
	8.	Altman, J.D. et al., "Phenotypic analysis of antigen-specific T lymphocytes" (1996) <i>Science</i> <b>274</b> (5284):94-96
	9.	Bertoni, R. et al., "Human class I supertypes and CTL repertoires extend to chimpanzees" (1998) <i>J. Immunol.</i> <b>161</b> :4447-4455
	10.	Boczowski, D. et al., "Dendritic cells pulsed with RNA are potent antigen-presenting cells in vitro and in vivo" (1996) <i>J. Exp. Med.</i> <b>184</b> :465-472
	11.	Bordignon, C. et al., "Retroviral vector-mediated high-efficiency expression of adenosine deaminase (ADA) in hematopoietic long-term cultures of ADA-deficient marrow cells" (1989) <i>PNAS USA</i> <b>86</b> :6748-6752
	12.	Carter, B.J., "Adeno-associated virus vectors" (1992) <i>Curr. Op. Biotechnol.</i> <b>3</b> :533-539
	13.	Caruso, A. et al., "Flow cytometric analysis of activation markers on stimulated T cells and their correlation with cell proliferation" (1997) <i>Cytometry</i> <b>27</b> :71-76
	14.	Correll, P.H. et al., "Production of human glucocerebrosidase in mice after retroviral gene transfer into multipotential hematopoietic progenitor cells" (1989) <i>PNAS USA</i> <b>86</b> :8912-8916
	15.	Coulie, P.G., "Human tumour antigens recognized by T cells: new perspectives for anti-cancer vaccines?" (1997) <i>Molec. Med. Today</i> <b>3</b> :261-268
	16.	Culver, K. et al., "Lymphocytes as cellular vehicles for gene therapy in mouse and man" (1991) <i>PNAS USA</i> <b>88</b> :3155-3159
	17.	Dharanipragada, R. et al., "The absolute configuration of an intermediate in the asymmetric synthesis of unusual amino acids" (1992) <i>Acta. Cryst.</i> <b>C48</b> :1239-1241
	18.	Dharanipragada, R. et al., "Synthetic linear and cyclic glucagon antagonists" (1993) <i>Int. J. Peptide Protein</i>

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	Res. 42(1):68-77		
19.	DiMaio, J. et al., "Synthesis of chiral piperazin-2-ones as model peptidomimetics" (1989) <i>J. Chem. Soc. Perkin Trans. 1</i> (9):1687-1689		
20.	Feltkamp, M.C.W. et al., "Competition inhibition of cytotoxic T-lymphocyte (CTL) lysis, a more sensitive method to identify candidate CTL epitopes than induction of antibody-detected MHC class I stabilization" (1995) <i>Immunol. Lett.</i> 47:1-8		
21.	Ferguson, et al. "Cell-surface anchoring of proteins via glycosyl-phosphatidylinositol structures" (1988) <i>Ann. Rev. Biochem.</i> 57:285-320		
22.	Fujihashi, K. et al., "Cytokine-specific ELISPOT assay single cell analysis of IL-2, IL-4 and IL-6 producing cells" (1993) <i>J. Immunol. Meth.</i> 160:181-189		
23.	Garvey D.S. et al., "3,4-disubstituted $\gamma$ -lactam rings as conformationally constrained mimics of peptide derivatives containing aspartic acid or norleucine" (1990) <i>J. Org. Chem.</i> 55(3):936-940		
24.	Hruby, V.J., "Conformational restrictions of biologically active peptides via amino acid side chain groups" (1982) <i>Life Sciences</i> 31:189-199		
25.	Hruby, V.J. et al. "Emerging approaches in the molecular design of receptor-selective peptide ligands: conformational, topographical and dynamic considerations" (1990) <i>Biochem J.</i> 268:249-262		
26.	Isakov, N. et al., "ZAP-70 binding specificity to T cell receptor tyrosine-based activation motifs: The tandem SH2 domains of ZAP-70 bind distinct tyrosine-based activation motifs with varying affinity" (1995) <i>J. Exp. Med.</i> 181:375-380		
27.	Jones, R.C.F. and G.J. Ward, "Amide bond isosteres: imidazolines in pseudopeptide chemistry" (1988) <i>Tetrahedron Lett.</i> 29(31):3853-3856		
28.	Kahn, M. and S. Bertenshaw, "The incorporation of $\beta$ -turn prosthetic units into merrifield solid phase peptide synthesis" (1989) <i>Tetrahedron Lett.</i> 30(18):2317-2320		
29.	Karlsson, S. et al., "Stable gene transfer and tissue-specific expression of a human globin gene using adenoviral vectors" (1986) <i>The EMBO J.</i> 5(9):2377-2385		
30.	Kawakami, Y. et al., "Cloning of the gene coding for a shared human melanoma antigen recognized by autologous T cells infiltrating into tumor" (1994) <i>PNAS USA</i> 91(9):3515-3519		
31.	Kazmierski, W. M. and V.J. Hruby, "Asymmetric synthesis of topographically constrained amino acids: synthesis of the optically pure isomers of $\alpha, \beta$ -dimethyl-phenylalanine and $\alpha, \beta$ -dimethyl-1,2,3,4-tetrahydroisoquinoline-3-carboxylic acid" (1991) <i>Tetrahedron Lett.</i> 32(41):5769-5772		
32.	Kazmierski, W.M. et al., "Topographic design of peptide neurotransmitters and hormones on stable backbone templates: relation of conformation and dynamics to bioactivity" (1991) <i>J. Am. Chem. Soc.</i> 113:2275-2283		
33.	Kemp, D.S. and P.E. McNamara, "Conformationally restricted cyclic nonapeptides derived from L-cysteine and LL-3-amino-2-piperidone-6-carboxylic acid (LL-Acp), a potent $\beta$ -turn-inducing dipeptide analogue" (1985) <i>J. Org. Chem.</i> 50:5834-5838		
34.	Kemp, D.S. and B.R. Bowen, "Conformational analysis of peptide-functionalized diacylaminoepindolidiones $^1\text{H}$ NMR evidence for $\beta$ -sheet formation" (1988) <i>Tetrahedron Lett.</i> 29(40):5081-5082		
35.	Kemp, D.S. and W.E. Stites, "A convenient preparation of derivatives of 3(S)-amino-10(R)-carboxy-1, 6-diaza-cyclodeca-2, 7-dione The dilactam of L- $\alpha$ , $\gamma$ -diaminobutyric acid and D-glutamic acid: A $\beta$ -turn template" (1988) <i>Tetrahedron Lett.</i> 29(40):5057-5060		
36.	Kemp, D.S. and T.P. Curran, "(2, 5S, 8S, 11S)-1-acetyl-1, 4-diaza-3-keto-5-carboxy-10-thia-tricyclo-[2.8.0 <sup>4,8</sup> ]-ridecane, 1 the preferred conformation of 1 (1= $\alpha$ temp-OH) and its peptide conjugates $\alpha$ temp-L-(Ala) <sub>n</sub> -OR (n=1 to 4) and $\alpha$ -temp -L-Ala-L-Phe-Lys( $\epsilon$ Boc)-L-Lys( $\epsilon$ -Boc)-NHMe studies of templates for $\alpha$ -helix		

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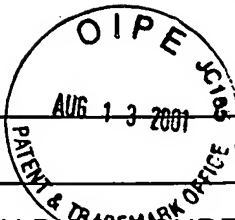
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	formation" (1988) <i>Tetrahedron Lett.</i> <b>29(39)</b> :4935-4938		
37.	Kemp, D.S. and J.S. Carter, "Amino acid derivatives that stabilize secondary structures of polypeptides. 4. Practical synthesis of 4-(alkylamino)-3-cyano-6-azabicyclo[3.2.1]oct-3-enes (ben derivatives) as $\gamma$ -turn templates" (1989) <i>J. Org. Chem.</i> <b>54</b> :109-115		
38.	McGrory, W.J. et al., "Short communications: A simple technique for the rescue of early region I mutation into infectious human adenovirus type 5" (1988) <i>Virology</i> <b>163</b> :614-617		
39.	Merrifield, R.B., "New approaches to the chemical synthesis of peptides" (1967) <i>Recent Progress in Hormone Res.</i> <b>23</b> :451-482		
40.	Miyake, A. et al., "Synthesis and angiotensin converting enzyme inhibitory activity of 1,2,3,4-tetrahydroisoquinoline-3-carboxylic acid derivatives" (1984) <i>J. Takeda Res. Labs.</i> <b>43(3/4)</b> :53-76		
41.	Mosier, D.E. et al., "Resistance to human immunodeficiency virus 1 infection of SCID mice reconstituted with peripheral blood leukocytes from donors vaccinated with vaccinia gp160 and recombinant gp160" (1993) <i>PNAS. USA</i> <b>90</b> :2443-2447		
42.	Muzyczka, "Use of adeno-associated virus as a general transduction vector for mammalian cells" (1992) <i>Curr. Top. Microbiol. Immunol.</i> <b>158</b> :97-129		
43.	Nagai, U. and K. Sato, "Synthesis of a bicyclic dipeptide with the shape of $\beta$ -turn central part" (1985) <i>Tetrahedron Lett.</i> <b>26(5)</b> :647-650		
44.	Nair, S. et al., "Soluble proteins delivered to dendritic cells via pH-sensitive liposomes induce primary cytotoxic T lymphocyte responses in vitro" (1992) <i>J. Exp. Med.</i> <b>175</b> :609-612		
45.	Olson, G.L. et al., "Design and synthesis of a protein $\beta$ -turn mimetic" (1990) <i>J. Am. Chem. Soc.</i> <b>112</b> :323-333		
46.	Paglia, P. et al., "Murine dendritic cells loaded in vitro with soluble protein prime cytotoxic T lymphocytes against tumor antigen in vivo" (1996) <i>J. Exp. Med.</i> <b>183</b> :317-322		
47.	Pardoll, D.M., "Cancer vaccines" (1998) <i>Nature Med.</i> <b>4(5 Suppl.)</b> :525-531		
48.	Parker, et al., "Sequence motifs important for peptide binding to the human MHC class I molecule, HLA-A2" (1992) <i>J. Immunol.</i> <b>149(11)</b> :3580-3587		
49.	Parker, K.C. et al. (1995) "Peptide Binding to MHC Class I Molecules: Implications for Antigenic Peptide Prediction" <i>Immunol. Res.</i> <b>14</b> :34-57.		
50.	Parkhurst, M.R. et al., "Improved induction of melanoma-reactive CTL with peptides from the melanoma antigen gp100 modified at HLA-A*0201-binding residues" (1996) <i>J. Immunol.</i> <b>157</b> :2539-2548		
51.	al-Ramadi, B.K. et al., "Lack of strict correlation of functional sensitization with the apparent affinity of MHC/peptide complexes for the TCR" (1992) <i>J. Immunol.</i> <b>155(2)</b> :662-673		
52.	Rill, D.R. et al., "An approach for the analysis of relapse and marrow reconstitution after autologous marrow transplantation using retrovirus-mediated gene transfer" (1992) <i>Blood</i> <b>79(10)</b> :2694-2700		
53.	Rouse, R.J.D. et al., "Induction in vitro of primary cytotoxic T-lymphocyte responses with DNA encoding herpes simplex virus proteins" (1994) <i>J. Virol.</i> <b>68(9)</b> :5685-5689		
54.	Salazar, E. et al., "Agonist peptide from a cytotoxic T-lymphocyte epitope of human carcinoembryonic antigen stimulates production of TC1-type cytokines and increases tyrosine phosphorylation more efficiently than cognate peptide" (2000) <i>Int. J. Cancer</i> <b>85</b> :829-838		
55.	Samanen, J. et al., "5,5-dimethylthiazolidine-4-carboxylic acid (DTC) as a proline analog with restricted conformation" (1990) <i>Int. J. Peptide Protein Res.</i> <b>35</b> :501-509		
56.	Schlesinger, S. and T.W. Dubensky, Jr., "Alphavirus vectors for gene expression and vaccines" (1999) <i>Curr Opin Biotechnol.</i> <b>10(5)</b> :434-439		
57.	Sette, A. et al., "The relationship between class I binding affinity and immunogenicity of potential cytotoxic		

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	T cell epitopes" (1994) <i>J. Immunol.</i> <b>153</b> (12):5586-5592	
58.	Shirai, M. et al., "CTL responses of HLA-A2.1-transgenic mice specific for hepatitis C viral peptides predict epitopes for CTL of humans carrying HLA-A2.1" (1995) <i>J. Immunol.</i> <b>154</b> :2733-2742	
59.	Stuber, G. et al., "HLA-A0201 and HLA-B7 binding peptides in the EBV-encoded EBNA-1, EBNA-2 and BZLF-1 proteins detected in the MHC class 1 stabilization assay. Low proportion of binding motifs for several HLA class 1 alleles in EBNA-1" (1995) <i>Int. Immunol.</i> <b>7</b> (4):653-663	
60.	Tan, L. et al., "An improved assembly assay for peptide binding to HLA-B*2705 and H-2K*class I MHC molecules" (1997) <i>J. Immunol. Meth.</i> <b>209</b> (1):25-36	
61.	Tanguay, S. and J.J. Killion, "Direct comparison of ELISPOT and ELISA-based assays for detection of individual cytokine-secreting cells" (1994) <i>Lymphokine Cytokine Res.</i> <b>13</b> (4):259-263	
62.	Valmori, D. et al., "Induction of potent antitumor CTL responses by recombinant vaccinia encoding a melan-A peptide analogue" (2000) <i>J. Immunol.</i> <b>164</b> (2):1125-1131	
63.	van der Burg, S.H. et al., "Immunogenicity of peptides bound to MHC class I molecules depends on the MHC-peptide complex stability" (1996) <i>J. Immunol.</i> <b>156</b> :3308-3314	
64.	Ware, C.F. et al., "Recognition of HLA-A2 mutant and variant target cells by an HLA-A2 allospecific human cytotoxic T lymphocyte line" (1983) <i>J. Immunol.</i> <b>131</b> (3):1312-1317	
65.	Wilchek, M. and E.A. Bayer, "The avidin-biotin complex in bioanalytical applications" (1988) <i>Anal. Biochem.</i> <b>171</b> :1-32	
66.	Ying, H. et al., "Cancer therapy using a self-replicating RNA vaccine" (1999) <i>Nat. Med.</i> <b>5</b> (7):823-827	
67.	Zabrocki, J. et al., "Conformational mimicry. 1. 1,5-disubstituted tetrazole ring as a surrogate for the cis amide bond" (1988) <i>J. Am. Chem. Sci.</i> <b>110</b> :5875-5880	
68.	Zechel, C. et al., "Synthetic glucagon antagonists and partial agonists" (1991) <i>Int. J. Pep. Protein Res.</i> <b>38</b> (2):131-138	
69.	Zuegel, et al., "Termination of peripheral tolerance to a T cell epitope by heteroclitic antigen analogues" (1998) <i>J. Immunol.</i> <b>161</b> (4):1705-1709	
70.	Zweerink, H.J. et al., "Presentation of endogenous peptides to MHC class I-restricted cytotoxic T lymphocytes in transport deletion mutant T2 cells" (1993) <i>J. Immunol.</i> <b>150</b> (5):1763-1771	

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